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| 10/772,809 | 02/05/2004 | Joel E. Bernstein | 41957-102748 | 5946 |

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| EXAMINER |
|---|
| CLAYTOR, DEIRDRE RENEE |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 08/21/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent-ch@btlaw.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/772,809 | BERNSTEIN, JOEL E. | |
| | Examiner | Art Unit | |
| | Renee Claytor | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-9,11,12,14,15 and 17* is/are pending in the application.

4a) Of the above claim(s) *1-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,11,12,14,15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Currently, claims 1-9, 11-12, 14-15 and 17 are pending. Claims 1-8 are withdrawn from consideration and claims 9, 11-12, 14-15 and 17 are under examination herein.

### *Response to Arguments*

Applicants have cancelled claims 13 and 16 which overcomes the 35 USC 112 rejection over those claims. Applicants have amended claim 17 to overcome the 35 USC 112 rejection and the rejection is hereby withdrawn.

Applicants argue over the 35 USC 102 rejection over Caruso. In particular, Applicants argue that Caruso requires an NMDA antagonist and thus does not anticipate the present claims because the present claims require a non-narcotic analgesic and a tricyclic antidepressant. Applicants assert that there is no teaching of Caruso that would lead one in the art to make a composition including an optional component, such as the optional NSAID of Caruso, and excluding an essential compound such as the NMDA antagonist.

The above arguments are considered persuasive and the 35 USC 102 rejection over Caruso is herby withdrawn. However, the reference is considered to be a good reference and will be used in the following 35 USC 103 rejection below.

Applicants argue over the 35 USC 102 rejection over Kakuyama et al. Applicants argue that Kakuyama et al. does not anticipate the current claims because Kakuyama et al. does not teach one composition but rather two drugs being taken. Applicants argue

that there is no indication from the results in Kakuyama that the administration of both amitryptiline and the NSAID provide better results than the amitryptiline alone.

The above arguments are considered persuasive in light of the newly amended claim which limits administration in a single pharmaceutically acceptable vehicle and the 35 USC 102 rejection over Kakuyama is hereby withdrawn.

Due to Applicants amendments to the claims, please see the following new grounds of rejection given below.

### *Claim Rejections – 35 USC 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 11, 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Crawford et al. (US Patent 4,579,846).

Crawford et al. teaches an anti-inflammatory composition for the treatment of gastric irritation that employs the anti-inflammatory piroxicam (a non-steroidal anti-inflammatory drug) with the antidepressant doxepin (a tricyclic anti-depressant; see abstract and column 3, lines 45-58, in particular). Crawford et al. teaches that piroxicam and doxepin are co-administered in a single, combined formulation (see column 3, lines 55-60, in particular). Crawford et al. also teaches that in a combined formulation, the proportion of each drug is the ratio of the total daily dosage of each drug when dosed

alone (see column 3, lines 55-68, in particular). Crawford et al. exemplifies a treatment composition comprising piroxicam and 20 mg doxepin with lactose and hydroxypropyl methylcellulose in a capsule (carriers; see Examples 7 and 9 and column 4, lines 1-10, in particular).

It is respectfully noted that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of' is being construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus the intended use recited in claim 9, namely that the composition is for treatment of chronic pain is not afforded patentable weight.

***Claim Rejections - 35 USC 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al. (US Patent 4,579,846) as applied to claims 9, 11, 14-15 above and in view of Caruso et al. (WO 98/50044) and Matheson et al. (Drugs 2001 May; 61(6): 833-865).

Crawford teaches a pharmaceutical composition comprised of a tricyclic antidepressant and a non-narcotic analgesic as discussed above.

Crawford does not teach the physiologically acceptable acid addition salt of the tricyclic antidepressant.

Caruso et al. teaches that it is known to provide the anti-depressant doxepin as a pain-relieving agent in the hydrochloride salt form (see page 4, in particular).

Matheson teaches that commonly used non-narcotic analgesics such as rofecoxib are used at doses up to 500 mg/day (see Abstract; meeting the limitation of 0.5 gm in claim 17). Matheson compares rofecoxib to other non-narcotic analgesics such as ibuprofen and naproxen, and was found to be similarly effective, and the doses used of ibuprofen and naproxen are 2400 mg/day and 1000 mg/day respectively see Osteoarthritis under Therapeutic Efficacy for example). Though the paper focuses on rofecoxib, it is compared to other common non-narcotic analgesics used in different

treatment paradigms that are used in doses that fall within the range claimed in claim 17.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the hydrochloride salt form of doxepin taught by Caruso et al, in the composition of Crawford et al, because Crawford et al. teaches the combination formed in a capsule, whereas Caruso et al. teaches that the hydrochloride salt form is a suitable form for the administration of the pharmaceutical drugs. Further, it would be obvious to a person of ordinary skill in the art to provide doses of the non-narcotic analgesic in the range of 0.5 gm to 2.5 gm daily per the teachings of Matheson because Matheson teaches that doses of several non-narcotic analgesics fall within the range claimed for various types of pain. Accordingly, one of ordinary skill in the art would have been motivated to provide the hydrochloride salt form with the expectation of achieving a composition suitable for pharmaceutical administration and to also provide doses of non-narcotic analgesics that fall in the range of 0.5 gm to 2.5 gm daily because these are doses that are commonly used for the treatment of different types of pain.

## ***Conclusion***

No claims are allowed.

## ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617